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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------|------------------|
| 10/009,138 | 11/26/2001 | Haviv Toledano | | 8246 |
| 7590 Haviv Toledano c/o David Metzman 693 Downing Street Teanec, NJ 07666 | | 03/26/2007 | EXAMINER DAWSON, GLENN K | |
| | | | ART UNIT 3731 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | | |
| 3 MONTHS | 03/26/2007 | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|------------------------------|------------------------|---------------------|--|
| | 10/009,138 | TOLEDANO, HAVIV | |
| Examiner | Art Unit | | |
| Glenn K. Dawson | 3731 | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 26 January 2007.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 56-72 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) Claim(s) 67-72 is/are allowed.
6) Claim(s) 56-66 is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____

5) Notice of Informal Patent Application

6) Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01-26-2007 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of the term: "superseded" is not understood. Do these steps occur in place of those in claim 56, or in addition but before the steps of claim 56?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler-'508 (or Wilk-'486) in view of Kuramoto-5395030.

Bessler and Wilk disclose the method as claimed including laparoscopically using an annular stapler with two spaced heads to staple two sections of colon together. The anvil is placed in one section and that section is ten sutured or stapled closed to form a butt end. The stapling head is placed in the other section of colon and it is then cinched with a suture or stapled closed as well. The anvil is drawn together with the stapling head to staple the sections together and a cutter cuts the excess tissue inside the lumen. However, it is not disclosed that the stapler is introduced through the mouth of

the patient. However, Kuramoto discloses that it is known to insert a stapler through the mouth of a patient to connect a section of colon to the stomach. It would have been obvious to have inserted the flexible stapler of Bessler or Wilk through the mouth of the patient as merely an obvious alternative route, especially in the event that the section to be removed and sutured together is very close to the stomach.

Claims 56,57,61-63,65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuramoto, et al.-5395030.

Kuramoto discloses a method of laparoscopically removing a section of colon and then placing an anvil head in one section of the colon, closing it with suture forming a butt end; placing the stapler head in the other section, closing that end, and then drawing the two heads together stapling the sections together and cutting the excess tissue in the lumen. Also disclosed is a method whereby an anvil head is separately introduced laparoscopically into the intestine; inserting a stapler head through the mouth of the patient and into the stomach. Attaching the anvil head to the stapler; closing one section forming a butt end; and drawing the heads together to staple the colon to the stomach. It is not disclosed that the stapler is inserted through the mouth and both sections ends are closed forming butt ends and the tissue is cut and stapled. It is also not disclosed that the 1st method is done using the embodiment with the separately attachable anvil head. It would have been obvious to have inserted the embodiment of fig. 3 through the mouth in the event that the section of colon to be removed is very near the stomach.

It also would have been obvious to have formed a partial closure of the stomach end about the cable 234 and to have used a cutter to cut the excess tissue to ensure a proper seal and adequate flow through the anastomosis without possible tissue obstruction.

Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuramoto-'030 in view of Bessler-'508.

Kuramoto makes obvious the invention as claimed with the exception of the use of a linear stapler to close the butt ends. However, Bessler discloses that such is a known alternative to suturing the ends closed. It would have been a mere obvious substitution of a known alternative means of closing the butt ends by using a linear stapler instead of a suture.

Response to Arguments

Applicant's arguments filed 01-26-2007 have been fully considered but they are not persuasive.

Bessler discloses in col. 15 lines 45-54 that the stapling device and colon resection can be done "laparoscopically". The procedure is not an open procedure. It is clear that this portion of the text allows for the rectal insertion of the stapler and laparoscopic removal of the colon section. There is nothing ambiguous about the text or that one skilled in the art would be able to perform or know how to perform the disclosed method.

Fig. 9 and the accompanying description of Wilk clearly set forth the use of a single annular cutter to form an anastomosis on two colon sections laparoscopically.

Allowable Subject Matter

Claims 67-72 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Glenn K Dawson
Primary Examiner
Art Unit 3731

Gkd
17 March 2007